Comments on techniques to address compelling evidence with a failure of 1-Point QC checks

Flagging Process for Scenarios 2 and 3

The following process is for gaseous pollutant data that fail to meet 1-point QC checks (or Zero/Span) but monitoring organization **have compelling reasons/evidence to consider the data valid** (scenarios #2 and 3)

1. The failed 1-point QC check must be reported to AQS.
2. Routine data within the time frame between the last acceptable check and the next passing check should be flagged with a "1" flag signifying failed critical criteria and a "V" flag signifying the data was reviewed and there is a compelling reason to consider the data valid.
3. Monitoring organization will include free form note information to AQS that provides the reason for considering the data valid. This comment can be entered via the web application on the maintain raw data form.
4. When a combination of a "1/V" flag is reported, EPA Regions will be required to concur with the data in order for it to be accepted. This process of regional concurrence is used for "BG" flagging (missing ozone data not likely to exceed level of standard) so the same procedure will be followed. An AQS procedure will need to be set up and we'll inform the Regions when it is ready.

Comments

Region 1 (Bob Judge and Peter Kahn)

Looks good. Added 3 words in red to attached memo to prevent a State from running and failing a p-check at one concentration, and then running another at a different (presumably higher) concentration, and saying that's compelling evidence of no problem.

For example, after the failure the monitoring organization reviewed the data, went out to the site did an "as is" QC check (at the same concentration), performance evaluation or multi-point verification (no adjustment to analyzer) which showed the analyzer was operating within the 1-point acceptance limits

Region 10 comment on Region 1 suggestion (Chris Hall)

While I agree with your line of thought Bob I think we are adding a requirement that we may not be able to justify. As long as both checks are in the require range I do not know how we can dictate that the two checks have to be at the same concentration to be acceptable.

Region 6 (Fran Verhalen)

R6 has one concern for item #4 in that we anticipate an added workload for regional staff on the concurrence flagging for the 1/V flags.

Region 9 (Mike Flagg)

Mike – a few concerns some process questions.

I think we echo the workload concern expressed by R6 and have issues with steps 3 and 4.

Generally, I think we agree that keeping in the "failed" checks and flagging the data in some way is a good ***recommendation***, but using these flags and EPA concurrence to dictate whether a dataset is "valid for regulatory use" fundamentally changes the way our states validate data and alters EPA's role in the data collection process and how we judge whether data is acceptable for regulatory use.

Again, the concern is that these decisions are driven by guidance and not grounded in regulation. A single failed check does NOT mean the data are "bad" or can't be used for NAAQS decisions… this is firmly grounded in the CFR. This process implies that if data not meeting guidance criteria are not flagged in AQS appropriately and not concurred on by EPA, the data can't be used? This oddly shifts the decision to use or not use data to whether or not a procedural (non-technical) recommendation has been met.

Also, this is an extremely slippery slope that suggests data validation should now be handled in AQS to accommodate concerns about not meeting criteria in EPA guidance documents. Also by moving "final" validation or concurrence to EPA reverses long standing roles on who is responsible for the quality of the data. EPA is not well positioned to judge the validity of the data on a description in AQS (or otherwise). This is exactly why the states are responsible for validation, have a QA system, or a QA officer.

On a high level, shifting ultimate decision making to AQS/EPA for ALL 1-point check validity has the potential to undermine the entire QA system.

We already have CFR requirements for appropriate oversight mechanisms (ANPs, QAPPs, and TSAs) used to determine whether agencies are meeting CFR requirements and following EPA guidance. This seems to be adding unnecessary and burdensome steps to the state's and EPA's responsibilities.

Final process question. I imagine our states would like a chance to comment on this, as it has policy, process, and workload implications for them…

Is there a plan to share this in draft form with the states?

To just add briefly to Michael's comments (Gwen Yoshimura)–

I think most of our agencies really appreciate AQS flagging guidance, so we might get a very positive response to having steps 1 and 2 as recommendations. Allowing states the opportunity to comment and discuss process/timing seems important as well, as Michael suggests.

Step 3 seems more appropriately handled outside of AQS (for example, seems appropriate for any such flags to be discussed in the annual data certification letter). Step 4 also seems like it is already inherently a part of data certification and that a separate EPA regional concurrence is unnecessary (a resource burden for us, and something the states may take issue with).

Region 8

If Step 3 were to remain in AQS:

> Would the free form comment on raw data be required on every hourly raw data value with the 1/V flag combination?
>
> If only on 1st hour, can AQS associate that comment with many hourly values?
>
> Any way to view the comment in AQS other than browsing raw data?

Region 10

I would like to echo the concerns and comments from both Michael and Gwen in R9. Though I do like the idea of monitoring agencies providing brief documentation in AQS for data which is tied to a failing QC check but which the monitoring agency believes should still be kept, I agree with Gwen that it would be more appropriate and less burdensome to have steps 3 and 4 tied to the annual data certification process rather than it be a separate stand-alone process. We are performing QC review and approving data on a monitor-by-monitor basis every May and this can easily be folded into the process (if it is not already inherent to it now).

And as with Michael/R9 I am not comfortable with enforcing guidance unless it has been incorporated into a monitoring agencies QAPP and/or SOPs.

Region 4

We have reviewed the proposed guidance, "Steps to accept data not meeting critical criteria but considered valid," and want to express our concerns regarding the reporting of failing 1-point QC checks to AQS, as well as offer you some alternate solutions. Foremost, 40 CFR Part 58, Appendix A, Section 5.1.1 states, "For each quarter, each PQAO **shall report** to AQS directly…the results of all **valid** measurement quality checks it has carried out during the quarter" (emphasis added). The proposed guidance conflicts with our interpretation of CFR – invalid checks (such as those conducted with a malfunctioning calibrator) must not be reported. It also goes against the revised guidance issued in the 2017 version of the QA Handbook (see Section 17). The issuance of this particular guidance would also be a reversal of all of the efforts and progress our SLTs have made in Region 4 in the past 3+ years – through development of Data Handling SOPs, improved QAPPs, training materials, and numerous corrective actions resulting from TSAs (including AQS corrections and data revalidation).

We do strongly support the use of AQS as a tool and believe it can be enhanced to help both EPA and our monitoring organizations with their data validation processes. With that, we have suggestions on alternate AQS modifications – including new null codes and QA qualifier flags -- that could potentially assist with this issue (e.g., increase transparency while adhering to CFR). We'd like the opportunity to discuss our proposed solutions with you in more detail. Would you be available for a conference call? If so, we would be available for a call tomorrow (Wednesday, April 26), or any day next week that is convenient to the both of you.

Thank you for your consideration. I hope we can talk with you soon.

R10 Doug Jager

I'd like to recommend that we discuss the difference between "failing" QC checks verse "valid" QC checks and how we document these in AQS. I think the memo could be strengthened with some clarity on this. I'd also like to ask for a "wish list item" that I doubt can be delivered. I think if AQS could support the flagging of the actual precision checks, and not just the routine data, the memo could be streamlined a little more and the mechanics of reviewing the data in AQS for this issue would be more effective.